

**Subpart G—Defect Action Levels****§ 110.110 Natural or unavoidable defects in food for human use that present no health hazard.**

(a) Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The Food and Drug Administration establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.

(b) Defect action levels are established for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information.

(c) Compliance with defect action levels does not excuse violation of the requirement in section 402(a)(4) of the act that food not be prepared, packed, or held under unsanitary conditions or the requirements in this part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of the act, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.

(d) The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of the act, regardless of the defect level of the final food.

(e) A compilation of the current defect action levels for natural or unavoidable defects in food for human use that present no health hazard may be obtained upon request from the Center for Food Safety and Applied Nutrition (HFS-565), Food and Drug Administra-

tion, 5100 Paint Branch Pkwy., College Park, MD 20740.

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**PART 111—CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKAGING, LABELING, OR HOLDING OPERATIONS FOR DIETARY SUPPLEMENTS****Subpart A—General Provisions**

Sec.

111.1 Who is subject to this part?

111.3 What definitions apply to this part?

111.5 Do other statutory provisions and regulations apply?

**Subpart B—Personnel**

111.8 What are the requirements under this subpart B for written procedures?

111.10 What requirements apply for preventing microbial contamination from sick or infected personnel and for hygienic practices?

111.12 What personnel qualification requirements apply?

111.13 What supervisor requirements apply?

111.14 Under this subpart B, what records must you make and keep?

**Subpart C—Physical Plant and Grounds**

111.15 What sanitation requirements apply to your physical plant and grounds?

111.16 What are the requirements under this subpart C for written procedures?

111.20 What design and construction requirements apply to your physical plant?

111.23 Under this subpart C, what records must you make and keep?

**Subpart D—Equipment and Utensils**

111.25 What are the requirements under this subpart D for written procedures?

111.27 What requirements apply to the equipment and utensils that you use?

111.30 What requirements apply to automated, mechanical, or electronic equipment?

111.35 Under this subpart D, what records must you make and keep?

**Subpart E—Requirement to Establish a Production and Process Control System**

111.55 What are the requirements to implement a production and process control system?